Guidance Agenda:
Guidances CDER is Planning to Develop During Calendar Year 2005

(See the Good Guidance Practices (GGPs) regulation on this Web page or 21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY — Advertising

- Achieving Fair Balance in Print and Broadcast Advertisements
- Outdoor Promotion
- Warning Letters

CATEGORY — Chemistry

- Individual Product Bioequivalence Recommendations
- Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes

CATEGORY — Clinical/Medical

- Acne Vulgaris: Development of Drug Products for Treatment
- Clinical Evaluation of Agents to Lower the Risk of Developing Sporadic Colorectal Adenomas
- Clinical Trial Design for the Treatment of Bacterial Blepharitis
- Clinical Trial Design for the Treatment of Bacterial Conjunctivitis
- Clinical Trial Design for the Treatment of Bacterial Corneal Ulcers
- Clinical Trial Design for the Treatment of Dry Eye
- Clinical Trial Design for the Treatment of Superficial Punctate Keratitis (SPK)
- Conducting and Submitting Virology Studies to the Division of Antiviral Drug Products
- Developing Analgesic Products for the Treatment of Pain
- Development and Evaluation of Drugs for Treatment and Prevention of Gingivitis
- Inhalational Anthrax (Symptomatic) - Developing Therapeutic Agents that Target Anthrax Toxin
- Patient Reported Outcomes (PRO)

CATEGORY — Clinical/Pharmacology

- Immediate Release to Modified Release Dosage Forms
- In Vitro Drug Metabolism/Drug Interaction – Guidance for Reviewers

CATEGORY — Combination Products

- Drug Diagnostic Co-Development

CATEGORY — Compliance

- Maintaining Adequate and Accurate Records During Clinical Investigations

CATEGORY — Drug Safety Information

- Useful Written Consumer Medication Information

CATEGORY — IND

- Consumer Product Safety Commission – Tamper Resistant Packaging for INDs
- End of Phase 2 Meetings

CATEGORY — Labeling

- Content and Format of the Clinical Pharmacology Section
- Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Drug Names and Dosage Forms
- Labeling Dietary Supplements for Women Who Are or Could Be Pregnant
- Labeling for Human Prescription Drug and Biological Products – Implementing the New Content and Format Requirements
- Pregnancy Labeling Revisions
- Target Product Profile
- Use of Pharmacologic/Therapeutic Classification in Approved Labeling
- Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format

CATEGORY — OTC

- Actual Use Trials
- Labeling Comprehension Studies for OTC Drug Products
- Labeling of Skin Protectants
- Topical Drug Products for Vaginal Yeast Infections

CATEGORY — Pharmacology/Toxicology

- Nonclinical Safety Evaluation of Reformulated Drug Products, Including Administration by an Alternate Route
- Safety Testing of Drug Metabolites

CATEGORY — Procedural

- Assessment of Abuse Potential of Drugs
- Determining Whether Human Research with a Radioactive Drug can be Conducted Under a Radioactive Drug Research Committee
- Dispute Resolution Involving Pediatric Labeling
- How to Comply With the Pediatric Research Equity Act
- Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals
- Process for Contracts and Written Requests Under the Best Pharmaceutical for Children Act
- Qualifying for Pediatric Exclusivity Under Section 505a of the Federal Food, Drug, and Cosmetic Act
- Safety Testing of Drug Metabolites

Note: Agenda items reflect guidances under development as of the date of this posting.